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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,436	12/08/2000	Mark Fitchmun	PS-001MF.P	2693
26990	7590	10/31/2003	EXAMINER	
DAVID B. WALLER & ASSOCIATES 5677 OBERLIN DRIVE SUITE 214 SAN DIEGO, CA 92121			LEUNG, JENNIFER A	
			ART UNIT	PAPER NUMBER
			1764	

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/733,436

Applicant(s)

FITCHMUN, MARK

Examiner

Jennifer A. Leung

Art Unit

1764

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see Attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: of the reasons set forth in the Final Office Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

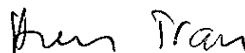
Claim(s) allowed: ---

Claim(s) objected to: ---

Claim(s) rejected: 1-3, 5-19 and 21.

Claim(s) withdrawn from consideration: 20.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



HIEU TRAN
PRIMARY EXAMINER

Response to Amendment

The proposed amendment(s) will not be entered because:

1. The newly added limitations to claims 1 and 21 change the scope of the claims, thus necessitating further search and/or consideration. In particular, the newly added limitation of “a composition comprising an absorbent matrix, a humectant, a pH-stabilizing agent and an adsorbent material,” differs in scope from the original claim, which recites “an absorbent matrix comprising a humectant, a pH-stabilizing agent and an adsorbent material.”
2. The newly added claims 22 and 23 present new issue, since the limitation of, “the pH-stabilization agent... present in sufficient quantity to prevent the formation of gas,” and “the composition, excepting the humectant, are substantially dry,” were not previously presented during prosecution, and therefore necessitate further search and/or consideration.
3. The subject matter of newly added claim 23 is drawn to new matter, as it is unclear as to where the proposed limitation of, “the composition, excepting the humectant, are substantially dry,” is located or supported in the disclosure.

Response to Arguments

Applicant's arguments filed on September 15, 2003 have been fully considered but they are not persuasive.

On page 7, paragraph 1, Applicant asserts,

“New claim 23 is supported by the *inherent* disclosure of the specification, claim 19 and Example 1.” (with emphasis added).

However, the Examiner respectfully disagrees with Applicant and submits that, “the components of the composition, excepting the humectant, are substantially dry,” is not inherent of the

disclosure. For example, on page 6, line 25 to page 7, line 1, the Specification discloses a variety of pH-stabilizing agents and further indicates that, “[t]hose skilled in the art would recognize that *any pH-stabilizing agent* that maintains the pH at a desired level... would be useful.” (with emphasis added). Therefore, it is unclear as to where in the disclosure the negative limitation of the components (excepting the humectant) cannot be wet, and thus must be dry, is supported.

On page 7, second to last paragraph, Applicant asserts,

“As used in the claims, the “absorbent matrix” “can take up or absorb liquid”. By themselves, the FASTABs described in Levy apparently do not contain buffer as prepared, and therefore do not meet the limitations of claim 14. Rather, *the cited composition of Levy is the combination of the FASTAB absorbing the buffer in the test tube*. The FASTABs can be used dehydrated, fully hydrated or partially hydrated. However, in each case, the FASTAB discs fail to meet limitations in claim 14.” (with emphasis added).

However, the Examiner respectfully disagrees with Applicant and contends that the Levy reference still meets the claim. In particular, claim 14 recites, “A composition comprising an absorbent matrix, a humectant, a pH stabilizing agent and adsorbent material.” In the rejection, the Examiner has indicated that the composition is to comprise the “combined composition”, per se, of all components added to the test tubes of Levy, including both the FASTAB (which contains the recited absorbent matrix, humectant and adsorbent material) and a buffer solution. As commonly defined, the word “composition” is the product of combining distinct parts or elements to form a whole. In the instant case, the FASTAB and buffer solution are each the “distinct parts or elements” and the combined “whole” forms the composition. Thus, taking the term literally, the “combined composition” of Levy meets the claim.

Additionally, on page 8, paragraph 5, Applicant asserts that the instantly claimed invention differs from the invention as disclosed by Levy because,

“A concentration of 13mM phosphate buffer, pH 7.6, would not be considered a “sufficient quantity to prevent the formation of gas” by one skill in the art in view of the teaching on page 6, lines 26-27 of the Specification.”

The cited page and line reference of the Specification states the following:

“The device may also comprise a pH-stabilizing agent that maintains the pH above a *desired level*. This is extremely important to prevent the formation of radioactive gas than can be formed under acidic conditions.” (with emphasis added).

However, it is noted that the “desired level” for establishing a “sufficient quantity” of pH-stabilizing agent to “prevent the formation of radioactive gas” is not taught in the disclosure, and therefore, one of ordinary skill in the art would not be able to assert that the quantity as taught by Levy is insufficient. Also, it is noted that the features upon which applicant relies (i.e., a “sufficient quantity” of “about 0.23M - 5M phosphate”; page 8, paragraph 6) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 19 currently recites, “about 1 to about 10 parts by weight of a *composition of disodium phosphate salts*” (with emphasis added), thus indicating that the molarity of the solution may lie outside the range of 0.23M - 5M as argued by applicants, since other agents (i.e., those encompassed in the recited “composition” of disodium phosphate salts) may contribute to the molarity of the solution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

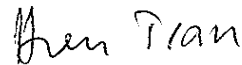
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on 703-308-6824. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung
October 28, 2003



HIEN TRAN
PRIMARY EXAMINER